IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS

ANGELS OF CARE HOME HEALTH, INC., Plaintiff,	§	
vs.	§	**CIVIL ACTION NO. 3:23-cv-2606**
XAVIER BECERRA, Secretary, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, Defendant.	§	

COMPLAINT FOR JUDICIAL REVIEW, ATTORNEY FEES, AND EXEMPLARY DAMAGES

COMES NOW, Angels of Care Home Health, Inc. (the "Plaintiff") by and through its attorneys or record and hereby files this its Complaint for Judicial Review, Attorney Fees, and Exemplary Damages against Defendant, Xavier Becerra, Secretary of the United States Department of Health and Human Services ("HHS" or the "Agency"), and alleges and avers as follows:

INTRODUCTION AND STATEMENT OF FACTS

1. Angels of Care Home Health, Inc., is a Medicare home care provider that delivers home health services to patients in their homes. Such care is critical, especially to elderly patients, that require assistance or have conditions that make leaving their homes a considerable and taxing effort. Home health services are covered by Medicare only if furnished by a home health agency participating in the Medicare program and acting on a physician's certification that the patient is confined to home, needs intermittent skilled nursing care or physician or occupational therapy or speech-language pathology services, and is under the care of a physician who has established a

plan of care. In effect, physicians determine whether a patient is eligible for home health services, and the home care provider furnishes services in accordance their plans of care.

2. On March 1, 2018, Qlarant, a Unified Program Integrity Contractor ("UPIC"), determined an extrapolated overpayment in the amount of $2,602,318.00. The UPIC extrapolated the overpayment using statistical sampling. The actual amount of the overpayment was $85,036.44, which was determined based upon a review of 40 claims submitted by the provider for payment. Of these claims, 32 were denied. The overpayment was then projected over a universe of 1,630 claims to obtain the $2,692,318.00 overpayment.

3. Plaintiff received data on the denials from Qlarant in a "Financial Sheet" recounting service dates for the 32 denied claims. For each of the claims, the dates of service reviewed were included, as was the HIPPS code for all or part of the payments that had already been made by CMS to Plaintiff for services. Other than a listing of general statements such as "Not Homebound – Home Health services did not meet Medicare coverage guidelines OR services not supported in Home Health record," limited explanation was given for Qlarant's denials. A document entitled "Provider Education" provided examples of certain claims not meeting Medicare criteria for skilled need, homebound status, the face-to-face encounter, and/or valid plan of care.

4. On March 8, 2018, Palmetto GBA, a Medicare Administrative Contractor ("MAC") notified Plaintiff of the $2,602,318.00 Medicare overpayment. According to the notice, the overpayment was based upon a post-pay investigation conducted by Qlarant and reflected the Medicare overpayment determination issued on March 1, 2018. The notice, however, was not accompanied by any of the essential statistical data used to calculate the overpayment, nor did it include critical evidence regarding the audit. This notice informed the provider of its administrative appeal rights.

5. On or about March 29, 2018, Plaintiff requested a redetermination of the overpayment determination pursuant to 42 C.F.R. §405.940 *et seq.*, that disputed and contested the overpayment determination. Plaintiff argued the UPIC had not followed the statutory and regulatory guidelines for denying payment on the home health services represented in the 32 claims on appeal, and that the medical records and documentation support the payment of the submitted claims. Further, Plaintiff asserted that the UPIC's cursory and limited assessment of the beneficiaries' medical histories and conditions cannot be substituted for the judgment of the physicians and practitioners who performed face-to-face assessments and issued orders for home health services. Finally, Plaintiff contended that the statistical sampling and methodology used to calculate the amount of the alleged overpayment was not conducted pursuant to statutory and regulatory guidelines, and, therefore, does not reflect a proper and accurate overpayment amount. The provider also alleged that the UPIC did not properly reopen the claims and has not presented good cause to have done so. Nor did it review the claims on a case-by-case basis so as to not jeopardize the beneficiaries in both the sample and the extrapolated universe.

6. On May 23, 2018, the MAC issued a partially favorable redetermination decision in which Plaintiff prevailed on its challenge to the statistical sampling and extrapolation methodology. However, only one day later, the MAC issued a fully unfavorable Corrected Redetermination Decision dated May 24, 2018.[1]

7. On or about July 18, 2018, Plaintiff requested a reconsideration of the MAC's decision arguing, among other things, that the UPIC had failed to adhere to statutory and regulatory guidelines in denying the clams comprising the sample, and that the medical records and

[1] On May 23, 2018, Plaintiff received a redetermination decision regarding a companion overpayment determination. This decision was partially favorable, and the statistical sampling review decision was favorable for Plaintiff. Thus, the alleged overpayment was reduced to $51,049.01. No corrected redetermination decision was ever sent to the provider concerning the companion overpayment.

documentation support the payment of the submitted claims. Further, Plaintiff asserted that the UPIC's cursory and limited assessment of the beneficiaries' medical histories and conditions cannot be substituted for the judgment of the physicians and practitioners who performed face-to-face assessments and issued order for home health services. Finally, Plaintiff contended that the statistical sampling and methodology used to calculate the amount of the alleged overpayment was not conducted pursuant to statutory and regulatory guidelines, and, therefore, does not reflect a proper and accurate overpayment amount. The provider also alleged that the UPIC did not properly reopen the claims and has not presented good cause to have done so. Nor did it review the claims on a case-by-case basis so as to not jeopardize the beneficiaries in both the sample and the extrapolated universe. On October 16, 2018, C2C Innovative Solutions, Inc., a Qualified Independent Contractor ("QIC"), issued an unfavorable decision on the overpayment determination and post-payment denials.

8. On October 25, 2018, the MAC issued a demand letter for the recalculated overpayment amount of $2,476,761.00 and Plaintiff filed its request for ALJ Hearing of the QIC's decision. The Request for ALJ decision was received by the Office of Medicare Hearings and Appeals on October 26, 2019.

9. Despite the statutorily mandated time periods governing the appeals process, in practice it takes a provider much longer to fully pursue its claim through the Medicare appeals process due to a previous backlog of Medicare appeals at the ALJ level, or the third stage of the Medicare Appeals process. In 2019, when Plaintiff filed its appeal, the average number of days for an appeal to be heard was 1,403.1 days. [2]

[2] Office of Medicare Hearings and Appeals (OMHA), Average processing time by Fiscal Year HHS.gov (2023), https://www.hhs.gov/about/agencies/omha/about/current-workload/average-processing-time-by-fiscal-year/index.html (last visited Nov 22, 2023).

10. Plaintiff was able to receive a hearing on May 13, 2022, or 932 days after it first requested the hearing. At the hearing, the Plaintiff provided expert testimony in support of the claims on appeal. On July 5, 2022, Plaintiff received a partially favorable decision where one (1) of the remaining 31 claims was found favorable.

11. On August 26, 2022, Plaintiff filed its request for Medicare Appeals Council review of the ALJ Decision pursuant to 42 C.F.R. §§405.1100-405.1140. The Council must issue a decision within ninety (90) calendar days. The Council's decision is the final agency action, and it is subject to judicial review. *See* 42 U.S.C. §1395ff; 42 C.F.R. §§405.1130, 405.1132, 405.1134; *see also* 42 U.S.C. §405(g).

12. Plaintiff, after not receiving a decision within the ninety (90) calendar days, filed a Request for Escalation on April 26, 2023, or 243 days after the filing of the Request for Medicare Council Review. After receiving no response, Plaintiff followed up on the Request for Escalation on July 24, 2023. After again receiving no response, Plaintiff filed a follow up letter on September 23, 2023. Plaintiff now files this Request for Judicial Review following the attempted requests for escalation from the Medicare Appeals Council pursuant to 42 C.F.R. §405.1132.

PARTIES

13. Angels of Care Home Health, Inc. in a home health agency participating in the Medicare program, and located in Dallas, Texas.

14. Defendant, Xavier Becerra, in his official capacity, is the Secretary of the United States Department of Health and Human Services ("HHS"), the governmental department which contains the Centers for Medicare and Medicaid Services ("CMS"), the agency within HHS that is responsible for administration of the Medicare and Medicaid programs. He may be served with process in accordance with Rule 4 of the Federal Rules of Civil Procedure by serving the U.S.

Attorney for the district where the action is brought, serving the Attorney General of the United States in Washington, D.C., by certified mail, and by serving the United States Department of Health and Human Services, by certified mail.

JURISDICTION AND VENUE

15. This action arises under the Medicare Act, a part of the Social Security Act at 42 U.S.C. §§ 1395 *et seq.* Plaintiff previously requested escalation from the Medicare Appeals Council and, after receiving no response, now escalates and requests Judicial Review. *See* 42 C.F.R. § 405.1132. Additionally, the Court has supplemental jurisdiction under 28 U.S.C. § 1367 over a certain number of Plaintiff's other claims because they are so related to the claims within the Court's original jurisdiction that they form part of the same case or controversy under Article 3 of the U.S. Constitution.

16. Plaintiff's principal office is located in Dallas, Texas, therefore, venue is proper in the Northern District of Texas, Dallas Division. *See* 42 U.S.C. §§ 405(g) and 1395ff(b).

APPLICABLE MEDICARE LAWS

The Medicare Program

17. As part of the Social Security Amendments of 1965, Congress established the Medicare program: a national health insurance plan to cover the cost of medical care for the elderly and disabled. *See* 42 U.S.C. §1395 *et seq*. Officially known as "Health Insurance Benefits for the Aged and Disabled," it provides basic protection against the costs of inpatient hospital and other institutional provider care. It also covers the costs of physician and other healthcare practitioner services and items not covered under the basic program. In 1997, beneficiaries were extended the option of choosing a managed care plan. More recently, in 2006, the program was expanded further to include a prescription drug benefit.

Home Health Services

18. Medicare covers home health services furnished to beneficiaries by home health agencies participating in the program. *See* 42 U.S.C. §1395x(m); 42 C.F.R. §409.40 *et seq*. A provider must act on a physician's certification that the individual is confined to the home, needs skilled nursing care on an intermittent basis or is in need of physical or occupational therapy, or speech-language pathology service, and is under the care of a physician who has established a plan of care. 42 C.F.R. §409.42. If the patient does not need therapy, skilled nursing care must be needed at least once every 60 days. *Id*.

Payment and Audit Functions

19. Medicare's payment and audit functions are performed by various federal contractors. For instance, the payment of home health claims at issue in this case was made by Palmetto GBA, LLC. Various other contractors, like Qlarant, a Unified Program Integrity Contractor ("UPIC"), investigate instances of suspected fraud, waste, and abuse as well as identify any improper payments that are to be collected by Administrative Contractors.

Appeal Process

20. Home health agencies participating in the Medicare program are entitled to appeal the initial action. *See* 42 U.S.C. §1395ff. Federal regulations establish an elaborate administrative appeal process to review the adverse action. *See* 42 C.F.R. Subpart I – Determination, Redeterminations, and Appeals Under Original Medicare. A provider dissatisfied with an initial determination may request a Redetermination by a contractor in accordance with 42 C.F.R. §§405.940-405.958. The Redetermination must be issued within sixty (60) calendar days. If a provider is dissatisfied with a Redetermination decision, it may request a Reconsideration by a Qualified Independent Contractor ("QIC") in accordance with 42 C.F.R. §§405.960-405.986. The

Reconsideration must be issued within sixty (60) calendar days. In the event the provider is dissatisfied with the Reconsideration decision, it may request an ALJ hearing in accordance with 42 C.F.R. §§405.1000-405.1054. The ALJ must issue a decision within ninety (90) calendar days. The provider may request review of the ALJ's decision by the Medicare Appeals Council in accordance with 42 C.F.R. §§405.1100-405.1140. The Council must issue a decision within ninety (90) calendar days. The Council's decision is the final agency action, and it is subject to judicial review. *See* 42 U.S.C. §1395ff; 42 C.F.R. §§405.1130, 405.1132, 405.1134; *see also* 42 U.S.C. §405(g).

Statistical Sampling and Extrapolation of Overpayments

21. Congress authorized HHS to "use extrapolation to determine overpayment amounts" if the Secretary determines that "there is a sustained or high level of payment error." 42 U.S.C. § 1395ddd(f)(3)(A); 42 C.F.R. § 405.926(p). Thus, the law allows extrapolation to be used to derive an overpayment from a statistically valid random sample of sampling units applied across the frame of sampling units. *See Chaves County Home Health Servs. v. Sullivan*, 931 F.2d 914 (D. C. Cir. 1991). Based on the legislature's instruction, the Secretary promulgated policy and rules on the framework for extrapolation, as permitted by statute. The Secretary's policy is encapsulated in CMS Rules 86-1-9 and 86-1-10. The Secretary's guidance, found in the Medicare Program Integrity Manual ("MPIM"), Pub. 100-08, Chap. 3, (eff. 5-10-04, now at MPIM Chap. 8, eff. 06-28-11), provides instructions to ensure that a "statistically valid sample is drawn and that statistically valid methods are used" to project an overpayment from the sample to the audit frame. The MPIM, which is not a statistics text, includes references upon which the theory of sampling and extrapolation are based. However, for an overpayment estimate to be valid, the laws and assumptions of probability and statistics must be met. *See* Robert D. Messer, M.D. & Assoc.,

Docket No. M-11-2534, Medicare Appeals Council (Dec. 11, 2011). In other words, the Secretary's policy and processes founded in statistics must comport with developed and articulated governing mathematical concepts and principles.

CONDITIONS PRECEDENT

22. All conditions precedent have been performed or have occurred.

CLAIMS FOR RELIEF

COUNT I

AGENCY ACTION IS ARBITRARY AND CAPRICIOUS.

23. Plaintiff hereby incorporates by reference the preceding paragraphs herein.

24. Based upon the administrative record developed before the Agency, the final decision is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.

25. Specifically, the Agency failed to adjudicate the appeal in accordance with the regulations and guidance governing home health claims. Plaintiff provided expert testimony at the hearing regarding the need for home health services. Such testimony should have been given substantial weight as to why the claims should have been approved.

26. Plaintiff disputes and contests that the ALJ properly determined that it submitted a Medicare claim in violation of the medical necessity requirement for each and every claim referenced in the exhibits. Specifically, the CMS Contractors have not followed the statutory and regulatory guidelines for denying payment on claims represented on appeal. (*See Caring Hearts Personal Home Services, Inc. v. Burwell*, No. 14-3243 (10th Cir. May 31, 2016). The claims submitted were properly presented and fully payable. The beneficiaries, indeed, assigned their rights to Plaintiff for the billing of claims to Medicare at the time of service. The claims were properly billed and supported by sufficient documents and records. The beneficiaries were in the

stated conditions as the records indicated, the home health services provided and billed were reasonable and medically necessary, ordered by the physician, and were not in excess of the physician's protocol. Specifically, the CMS homebound definition allows beneficiaries to take walks around the block, go for drives, and to go to church or friends without negating the homebound determination of the physician and the nurse. These scientific possibilities are sidestepped by relying solely on the beneficiary's rare outing to visit family or attend religious services. These patients were referred to the provider by physicians who have determined that they are "homebound" and eligible to receive home health services. To be eligible for home health services, the patient's physician must certify he or she is confined to the home. This means that for the patient were exists "a normal inability to leave home" and to do so would require "a considerable and taxing effort." Medicare rules expressly provide that a patient can meet the homebound requirement yet be absent from the come for "an infrequent or short duration." Patients may leave their homes to receive health care treatment and for nonmedical purposes, like "an occasional trip to the barber, a walk around the block or a drive, attendance at a family reunion, funeral, graduation, a trip to the grocery store" or other similar event. *See* Medicare Benefits Policy Manual, Pub. No. 100-02, Ch.7, Sec. 30.1.1.

27. Plaintiff disputes and contests that the alleged overpayment determination is based upon the proper analysis for the reasons for denial given as the basis for the denial of payment. Plaintiff argues that this analysis does not comply with statutory, regulation, or interpretive guidelines. Specifically, in the Medicare Benefits Policy Manual, Chapter 7, Section 20.3, CMS clearly states that "[M]edicare recognizes that determinations of whether home health services are reasonable and necessary must be based on an assessment of each beneficiary's individual care needs." The "Rules of Thumb" prohibition mandates that coverage of home services must be

determined based on the "unique medical condition of the individual beneficiary." *See* 42 C.F.R. § 409.44(a). Coverage denials are not to be made solely on the basis of a reviewer's general inferences about patients with similar diagnoses or on data related to utilization generally but based upon objective clinical evidence regarding the beneficiary's individual need for care. Id. Because each beneficiary receiving home health services is determined to be homebound and to need the medical services on their own merits, a "rule of thumb" cannot be utilized to determine whether services are covered or not. Each beneficiary must be reviewed. Therefore, only the claims that were actually reviewed can be used to calculate an overpayment in this instance. The only overpayment at issue is the overpayment calculated from the sample of claims. No other records were reviewed by the Contractor and no extrapolation can be utilized in this instance.

28. The ALJ erred in regards to sustaining the statistical sampling in this matter. Specifically, on May 23, 2018, Palmetto issued a Redetermination Decision on the claims on appeal. The decision was partially favorable. Specifically, Palmetto issued a favorable decision on review of Plaintiff's challenge to the statistical sampling methodology. The May 23rd Redetermination Decision indicated that the confidence level drops somewhat below the 90% level prescribed by the Medicare Program Integrity Manual ("PIM"). On May 24, 2018, only one day after Palmetto issued its Redetermination Decision, a Corrected Redetermination Decision was issued. The decision was partially favorable; however, Palmetto's decision on review of Plaintiff's challenge to the statistical sampling methodology was now unfavorable. Because of the conflicting decisions, the ALJ erred in not finding the statistical sampling and extrapolation invalid.

COUNT II

VIOLATION OF PROCEDURAL DUE PROCESS OF LAW

29. Plaintiff hereby incorporates by reference the preceding paragraphs herein.

30. The Fifth and Fourteenth Amendments to the U.S. Constitution guarantee that no person shall be deprived of life, liberty, or property without Due Process of Law.

31. Specifically, the Agency failed to adjudicate the appeal in accordance with the regulations and guidance governing home health claims as well as failed to timely adjudicate the claims. Plaintiff provided expert testimony at the hearing regarding the need for home health services. Such testimony should have been given substantial weight as to why the claims should have been approved.

32. Plaintiff disputes and contests that the ALJ properly determined that it submitted a Medicare claim in violation of the medical necessity requirement for each and every claim referenced in the exhibits. Specifically, the CMS Contractors have not followed the statutory and regulatory guidelines for denying payment on claims represented on appeal. (*See Caring Hearts Personal Home Services, Inc. v. Burwell*, No. 14-3243 (10th Cir. May 31, 2016). The claims submitted were properly presented and fully payable. The beneficiaries, indeed, assigned their rights to Plaintiff for the billing of claims to Medicare at the time of service. The claims were properly billed and supported by sufficient documents and records. The beneficiaries were in the stated conditions as the records indicated, the home health services provided and billed were reasonable and medically necessary, ordered by the physician, and were not in excess of the physician's protocol. Specifically, the CMS homebound definition allows beneficiaries to take walks around the block, go for drives, and to go to church or friends without negating the homebound determination of the physician and the nurse. These scientific possibilities are sidestepped by relying solely on the beneficiary's rare outing to visit family or attend religious services. These patients were referred to the provider by physicians who have determined that they are "homebound" and eligible to receive home health services. To be eligible for home health

services, the patient's physician must certify he or she is confined to the home. This means that for the patient were exists "a normal inability to leave home" and to do so would require "a considerable and taxing effort." Medicare rules expressly provide that a patient can meet the homebound requirement yet be absent from the come for "an infrequent or short duration." Patients may leave their homes to receive health care treatment and for nonmedical purposes, like "an occasional trip to the barber, a walk around the block or a drive, attendance at a family reunion, funeral, graduation, a trip to the grocery store" or other similar event. *See* Medicare Benefits Policy Manual, Pub. No. 100-02, Ch.7, Sec. 30.1.1.

33. Plaintiff disputes and contests that the alleged overpayment determination is based upon the proper analysis for the reasons for denial given as the basis for the denial of payment. Plaintiff argues that this analysis does not comply with statutory, regulation, or interpretive guidelines. Specifically, in the Medicare Benefits Policy Manual, Chapter 7, Section 20.3, CMS clearly states that "[M]edicare recognizes that determinations of whether home health services are reasonable and necessary must be based on an assessment of each beneficiary's individual care needs." The "Rules of Thumb" prohibition mandates that coverage of home services must be determined based on the "unique medical condition of the individual beneficiary." *See* 42 C.F.R. § 409.44(a). Coverage denials are not to be made solely on the basis of a reviewer's general inferences about patients with similar diagnoses or on data related to utilization generally but based upon objective clinical evidence regarding the beneficiary's individual need for care. Id. Because each beneficiary receiving home health services is determined to be homebound and to need the medical services on their own merits, a "rule of thumb" cannot be utilized to determine whether services are covered or not. Each beneficiary must be reviewed. Therefore, only the claims that were actually reviewed can be used to calculate an overpayment in this instance. The only

overpayment at issue is the overpayment calculated from the sample of claims. No other records were reviewed by the Contractor and no extrapolation can be utilized in this instance.

34. The ALJ erred in regards to sustaining the statistical sampling in this matter. Specifically, on May 23, 2018, Palmetto issued a Redetermination Decision on the claims on appeal. The decision was partially favorable. Specifically, Palmetto issued a favorable decision on review of Plaintiff's challenge to the statistical sampling methodology. The May 23rd Redetermination Decision indicated that the confidence level drops somewhat below the 90% level prescribed by the Medicare Program Integrity Manual ("PIM"). On May 24, 2018, only one day after Palmetto issued its Redetermination Decision, a Corrected Redetermination Decision was issued. The decision was partially favorable; however, Palmetto's decision on review of Plaintiff's challenge to the statistical sampling methodology was now unfavorable. Because of the conflicting decisions, the ALJ erred in not finding the statistical sampling and extrapolation invalid.

COUNT III

AGENCY ACTION IS CONTRARY TO CONSTITUTIONAL RIGHT

35. Plaintiff hereby incorporates by reference the preceding paragraphs herein.

36. The Fifth and Fourteenth Amendments to the U.S. Constitution guarantee that no person shall be deprived of life, liberty, or property without Due Process of Law.

37. Specifically, the Agency failed to adjudicate the appeal in accordance with the regulations and guidance governing home health claims. Plaintiff provided expert testimony at the hearing regarding the need for home health services. Such testimony should have been given substantial weight as to why the claims should have been approved.

38. Plaintiff disputes and contests that the ALJ properly determined that it submitted a Medicare claim in violation of the medical necessity requirement for each and every claim

referenced in the exhibits. Specifically, the CMS Contractors have not followed the statutory and regulatory guidelines for denying payment on claims represented on appeal. (*See Caring Hearts Personal Home Services, Inc. v. Burwell*, No. 14-3243 (10th Cir. May 31, 2016). The claims submitted were properly presented and fully payable. The beneficiaries, indeed, assigned their rights to Plaintiff for the billing of claims to Medicare at the time of service. The claims were properly billed and supported by sufficient documents and records. The beneficiaries were in the stated conditions as the records indicated, the home health services provided and billed were reasonable and medically necessary, ordered by the physician, and were not in excess of the physician's protocol. Specifically, the CMS homebound definition allows beneficiaries to take walks around the block, go for drives, and to go to church or friends without negating the homebound determination of the physician and the nurse. These scientific possibilities are sidestepped by relying solely on the beneficiary's rare outing to visit family or attend religious services. These patients were referred to the provider by physicians who have determined that they are "homebound" and eligible to receive home health services. To be eligible for home health services, the patient's physician must certify he or she is confined to the home. This means that for the patient were exists "a normal inability to leave home" and to do so would require "a considerable and taxing effort." Medicare rules expressly provide that a patient can meet the homebound requirement yet be absent from the come for "an infrequent or short duration." Patients may leave their homes to receive health care treatment and for nonmedical purposes, like "an occasional trip to the barber, a walk around the block or a drive, attendance at a family reunion, funeral, graduation, a trip to the grocery store" or other similar event. *See* Medicare Benefits Policy Manual, Pub. No. 100-02, Ch.7, Sec. 30.1.1.

39. Plaintiff disputes and contests that the alleged overpayment determination is based upon the proper analysis for the reasons for denial given as the basis for the denial of payment. Plaintiff argues that this analysis does not comply with statutory, regulation, or interpretive guidelines. Specifically, in the Medicare Benefits Policy Manual, Chapter 7, Section 20.3, CMS clearly states that "[M]edicare recognizes that determinations of whether home health services are reasonable and necessary must be based on an assessment of each beneficiary's individual care needs." The "Rules of Thumb" prohibition mandates that coverage of home services must be determined based on the "unique medical condition of the individual beneficiary." *See* 42 C.F.R. § 409.44(a). Coverage denials are not to be made solely on the basis of a reviewer's general inferences about patients with similar diagnoses or on data related to utilization generally but based upon objective clinical evidence regarding the beneficiary's individual need for care. Id. Because each beneficiary receiving home health services is determined to be homebound and to need the medical services on their own merits, a "rule of thumb" cannot be utilized to determine whether services are covered or not. Each beneficiary must be reviewed. Therefore, only the claims that were actually reviewed can be used to calculate an overpayment in this instance. The only overpayment at issue is the overpayment calculated from the sample of claims. No other records were reviewed by the Contractor and no extrapolation can be utilized in this instance.

40. The ALJ erred in regards to sustaining the statistical sampling in this matter. Specifically, on May 23, 2018, Palmetto issued a Redetermination Decision on the claims on appeal. The decision was partially favorable. Specifically, Palmetto issued a favorable decision on review of Plaintiff's challenge to the statistical sampling methodology. The May 23rd Redetermination Decision indicated that the confidence level drops somewhat below the 90% level prescribed by the Medicare Program Integrity Manual ("PIM"). On May 24, 2018, only one day

after Palmetto issued its Redetermination Decision, a Corrected Redetermination Decision was issued. The decision was partially favorable; however, Palmetto's decision on review of Plaintiff's challenge to the statistical sampling methodology was now unfavorable. Because of the conflicting decisions, the ALJ erred in not finding the statistical sampling and extrapolation invalid.

COUNT IV

AGENCY ACTION IS IN EXCESS OF STATUTORY AUTHORITY

41. Plaintiff hereby incorporates by reference the preceding paragraphs herein.

42. The Fifth and Fourteenth Amendments to the U.S. Constitution guarantee that no person shall be deprived of life, liberty, or property without Due Process of Law.

43. Specifically, the Agency failed to adjudicate the appeal in accordance with the regulations and guidance governing home health claims. Plaintiff provided expert testimony at the hearing regarding the need for home health services. Such testimony should have been given substantial weight as to why the claims should have been approved.

44. Plaintiff disputes and contests that the ALJ properly determined that it submitted a Medicare claim in violation of the medical necessity requirement for each and every claim referenced in the exhibits. Specifically, the CMS Contractors have not followed the statutory and regulatory guidelines for denying payment on claims represented on appeal. (*See Caring Hearts Personal Home Services, Inc. v. Burwell*, No. 14-3243 (10th Cir. May 31, 2016). The claims submitted were properly presented and fully payable. The beneficiaries, indeed, assigned their rights to Plaintiff for the billing of claims to Medicare at the time of service. The claims were properly billed and supported by sufficient documents and records. The beneficiaries were in the stated conditions as the records indicated, the home health services provided and billed were reasonable and medically necessary, ordered by the physician, and were not in excess of the

physician's protocol. Specifically, the CMS homebound definition allows beneficiaries to take walks around the block, go for drives, and to go to church or friends without negating the homebound determination of the physician and the nurse. These scientific possibilities are sidestepped by relying solely on the beneficiary's rare outing to visit family or attend religious services. These patients were referred to the provider by physicians who have determined that they are "homebound" and eligible to receive home health services. To be eligible for home health services, the patient's physician must certify he or she is confined to the home. This means that for the patient were exists "a normal inability to leave home" and to do so would require "a considerable and taxing effort." Medicare rules expressly provide that a patient can meet the homebound requirement yet be absent from the come for "an infrequent or short duration." Patients may leave their homes to receive health care treatment and for nonmedical purposes, like "an occasional trip to the barber, a walk around the block or a drive, attendance at a family reunion, funeral, graduation, a trip to the grocery store" or other similar event. *See* Medicare Benefits Policy Manual, Pub. No. 100-02, Ch.7, Sec. 30.1.1.

45. Plaintiff disputes and contests that the alleged overpayment determination is based upon the proper analysis for the reasons for denial given as the basis for the denial of payment. Plaintiff argues that this analysis does not comply with statutory, regulation, or interpretive guidelines. Specifically, in the Medicare Benefits Policy Manual, Chapter 7, Section 20.3, CMS clearly states that "[M]edicare recognizes that determinations of whether home health services are reasonable and necessary must be based on an assessment of each beneficiary's individual care needs." The "Rules of Thumb" prohibition mandates that coverage of home services must be determined based on the "unique medical condition of the individual beneficiary." *See* 42 C.F.R. § 409.44(a). Coverage denials are not to be made solely on the basis of a reviewer's general

inferences about patients with similar diagnoses or on data related to utilization generally but based upon objective clinical evidence regarding the beneficiary's individual need for care. Id. Because each beneficiary receiving home health services is determined to be homebound and to need the medical services on their own merits, a "rule of thumb" cannot be utilized to determine whether services are covered or not. Each beneficiary must be reviewed. Therefore, only the claims that were actually reviewed can be used to calculate an overpayment in this instance. The only overpayment at issue is the overpayment calculated from the sample of claims. No other records were reviewed by the Contractor and no extrapolation can be utilized in this instance.

46. The ALJ erred in regards to sustaining the statistical sampling in this matter. Specifically, on May 23, 2018, Palmetto issued a Redetermination Decision on the claims on appeal. The decision was partially favorable. Specifically, Palmetto issued a favorable decision on review of Plaintiff's challenge to the statistical sampling methodology. The May 23rd Redetermination Decision indicated that the confidence level drops somewhat below the 90% level prescribed by the Medicare Program Integrity Manual ("PIM"). On May 24, 2018, only one day after Palmetto issued its Redetermination Decision, a Corrected Redetermination Decision was issued. The decision was partially favorable; however, Palmetto's decision on review of Plaintiff's challenge to the statistical sampling methodology was now unfavorable. Because of the conflicting decisions, the ALJ erred in not finding the statistical sampling and extrapolation invalid.

COUNT V

AGENCY ACTION IS WITHOUT OBSERVANCE OF PROCEDURE AND IS UNSUPPORTED BY SUBSTANTIAL EVIDENCE

47. Plaintiff hereby incorporates by reference the preceding paragraphs herein.

48. Based upon the administrative record developed before the Agency, the final administrative decision is without observance of procedure required by law. Specifically, the

statistical sampling and extrapolation should be invalidated due to the failure to notify the beneficiaries.

49. Based upon the administrative record developed before the Agency, the final administrative decision is unsupported by substantial evidence.

COUNT VI

ULTRA VIRES ACTIONS

50. Plaintiff hereby incorporates by reference all preceding paragraphs of this complaint as if fully set forth herein.

51. Defendant acts *ultra vires* in failing to conduct the administrative process pursuant to statutes and regulations required including adjudicating an appeal timely.

COUNT VII

DAMAGES

52. As a direct and proximate result of Defendant's conduct, Plaintiff suffered the following damages:

a. actual damages in that Defendant is improperly collecting an overpayment that was, and should be, invalidated.

b. lost profits.

EXEMPLARY DAMAGES

53. Plaintiff hereby incorporates by reference the preceding paragraphs herein.

54. For Defendant's egregious conduct towards Plaintiff and reckless disregard of Plaintiff's Due Process rights under law, Plaintiff seeks exemplary damages.

ATTORNEY FEES AND COSTS

55. Plaintiff is entitled to an award of attorney fees and costs under the Equal Access to Justice Act, pursuant to 28 U.S.C. § 2412(d)(1)(A), upon showing the applicant is a "prevailing party"; a showing that the applicant is "eligible to receive an award"; and a statement of "the amount sought, including an itemized statement from any attorney . . . stating the actual time expended and the rate" charged. The prevailing party is entitled to such attorney fees unless the government's position was "substantially justified" or special circumstances make an award unjust.

PRAYER

56. For these reasons, Plaintiff prays for judgment against Defendants and setting aside the Secretary's final agency action as unlawful based upon the following reasons:

a) the Agency action is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

b) the Agency action is a violation of Plaintiff's procedural Due Process of law;

c) the Agency action is contrary to constitutional right, power, privilege, or immunity;

d) the Agency action is in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

e) the Agency action is without observance of procedure required by law;

f) the Agency action is unsupported by substantial evidence;

g) assess damages and exemplary damages against Defendant;

h) assess prejudgment and post-judgment interest against Defendant;

i) assess reasonable attorney fees and costs of suit;

j) for such other and further relief as the Court may deem just and proper under law..

Respectfully submitted,

KENNEDY
Attorneys and Counselors at Law

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